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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

936,198

Applicant(s)

GLEN et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/18/04
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-8, 10-25, 27-33 is/are pending in the application.
- Of the above claim(s) 27-33 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 16-25 is/are rejected.
- ☒ Claim(s) 1-8, 10-15 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Amendment of 7/18/04 has been entered. Claims 1-8, 10-25 and 27-33 are pending.

Claims 1-8 and 10-25 are under examination. The amendment has entered no new matter.

The amendment has overcome previously stated issues as follows:

The objection to claims 3-4 and 17.

The rejection of claims 2-7, 11, 14-16, 19-21, 24 and 26 under 35 USC 112, 2nd paragraph.

The rejection of claims 1-26 under 35 USC 112, 1st paragraph.

The rejection of claims 1-19 and 26 under 35 USC 112, 1st paragraph.

The prior art rejections based upon Filimonkova.

The following objections/rejections of record are maintained or modified as follows:

Claims 1, 5-7 and 16 are objected to under 37 CFR 1.75(i), as being of improper dependent form for failing to indent each active verb step. Applicant did not address this ground of objection with respect to claims 1 and 16. This ground of objection is newly applied to claims 5-7, because applicant's amendment has introduced two active verb steps in each claim.

Claims 16-17 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 17 adds nothing to further define claim 1. Claim 17, step a) adds nothing to further define claim 1. Claim 19 adds nothing to further define claim 1. See further discussion under 112, 2nd para.

Claim 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is unclear by reciting "detecting the proteins ex vivo" because "obtaining a sample of red blood cells separated from whole blood, and detecting..." (claim 1, lines 3-4) necessarily involves preparing an "ex vivo" sample.

In claim 17, step a) "the other blood components" lack antecedent basis. It is also unclear what step a) adds to recitation in claim 1 of "obtaining a sample of red blood cells separated from whole blood".

In claim 17, step b) "directly" is unclear, since one does not know what "separating the proteins "directly" means in contrast to simply "separating the proteins".

Claim 19 is unclear by reciting "detected by immunoassay", since claim 1 requires detecting "with an antibody". Any detection method using an antibody (e.g. immunoprecipitation, gel diffusion, agglutination, radioimmunoassay, ELISA) may be considered as an "immunoassay"; thus it is not clear what claim 19 adds to claim 1.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481

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(Bd. App. 1949). In the present instance, claims 20-24 recite the broad recitation "human monocyte", and the claims also recite "(U937)" which is the narrower statement of the range/limitation.

Since the rejection of claims 20-24 for reciting "(U937)" is a minor, newly stated rejection under 112, 2nd paragraph; the examiner shall consider any correction of these claims in an after FINAL amendment. Examples of correction are: 1) deletion of "(U937)" in each claim, or 2) deletion of "(U937)" in each claim and recitation thereof in a new, further dependent claim. If applicant presents new such dependent claims they will be the only new claims considered without the cancellation of a corresponding number of previously examined claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

This application contains claims 27-33 drawn to an invention nonelected with traverse in Paper filed 10/29/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 571-272-0849.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0849. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644